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The effectiveness of online mindfulness-based cancer recovery program on psychological Variables of colorectal and stomach cancer patients: A randomized control trial

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ABSTRACT

Background: This study aimed to investigate the effectiveness of an online version of a mindfulness-based recovery program (E-MBCR) on stress, cancer-related fatigue, and sleep disturbances in colorectal and stomach cancer patients. **Method:** In a randomized controlled trial, 50 cancer patients (34% colon, 28% rectum, 38% stomach) were recruited by convenience sampling from oncology departments of two hospitals and were randomly allocated to intervention (n=25) and control groups (n=25). The experimental group participated in a 9-week online mindfulness-based cancer recovery program. Outcome measures were assessed at three phases (pre-test, post-test, and two-months follow-up) by DASS-21, fatigue symptom subscale of QLQ-C30, and the Insomnia severity index. **Results:** Mixed linear models revealed significant improvements in cancer-related symptoms, including stress ($F=43.01$, $P=0.00$, $\eta^2=0.50$), fatigue ($F=33.40$, $P=0.00$, $\eta^2=0.43$), and sleep disturbances ($F=39.14$, $P=0.00$, $\eta^2=0.47$), in colorectal and stomach cancer patients. **Conclusion:** E-MBCR can be considered as having potential utility to ameliorate cancer patients' psychological disturbances.

Keywords: Mindfulness Cancer Recovery Program, Colorectal cancer, Stomach cancer, fatigue, stress, sleep problems.

1. INTRODUCTION

Cancer may be a pivotal worldwide wellbeing concern (Siegel et al., 2014). Based on the world health organization (WHO) cancer is growing with an

accelerating drift and is predicted to grow five-fold till 2030 (Boyle et al., 2008). Among all cancer sorts, stomach and colorectal cancers are the second and fourth driving sources of cancer-related passing (Bray et al., 2018). In Iran, epidemiological investigations report an increasing number of both stomach and colorectal cancers in the common population (Pourhoseingholi et al., 2016). Diagnosis of cancer has deteriorating negative consequences on patients' both physical and psychological life facets (Weib et al., 2018). Studies have shown that numerous patients battle with mental problems including elevated stress (Mravec et al., 2020).

Psychological stress emerges from the uncontrollability and life-threatening nature of the disease, patients' sense of helplessness, future uncertainties, and desperation in achieving life goals besides negative physical and psychological alterations in life (Sedek, 2001; Łosiak, 1999). Stress is not only a comorbid sign of cancer but also displays a significant role in the initiation of the disease and its progression (Everson & Kaplan, 1996). Studies reveal that stress can even adversely affect immune system functions and cause immune dysfunctional reactivity (Perrella et al., 2009). In addition to stress which is prevalently found in cancer patients, another intolerable issue that patients usually speak about is unpleasant, chronic, distressing, and activity-limiting fatigue which overshadows their whole life (Cella et al., 2002).

Fatigue is the foremost common unrelieved side effect of cancer (Cella et al., 1998; Stone et al., 2000; Stone et al., 1998). Assuming fatigue as a symptom and a side effect of cancer, it is defined as a subjective sensation of weakness, and overwhelming tiredness (Stone et al., 1998), and as a syndrome has been characterized as an over powering sense of depletion and diminished capacity for physical and mental work (Herdman, 2018). The prevalence of fatigue in cancer patients is reported to be 59%–100% (Servaes et al., 2002). The issue of fatigue in cancer patients is so evident that even a diagnostic criterion for cancer-related fatigue [CRF] is proposed (Cella et al., 1998). The prevalence of CRF is also reported in colorectal and stomach cancer patients (Mota et al., 2012; Hwang et al., 2014).

One of the simultaneous side effects of CRF which is commonly reported by cancer survivors is sleep disturbance (Savard & Morin, 2001; Hickok et al., 2005). Insomnia, short sleep duration, and poor sleep quality are common sleep-related problems in cancer patients (Owen et al., 1999), so that, 25% to 50% of all cancer prescriptions are allocated for insomnia (Stafford et al., 2015). Among all cancer types, stomach and colorectal patients are not an exception. Existing studies demonstrate the co-existence of sleep disturbance and fatigue in colorectal cancers (Coles et al., 2018). Sleep is a major problem for many of these patients. The prevalence estimates show that the risk of insomnia symptoms is escalating three-fold in cancer patients, and even years after cancer treatment it persists in 44% of patients (Savard & Morin, 2001; Savard & Savard, 2013), and regarding colorectal and stomach survivors it has been well- demonstrated that fatigue and insomnia are the most prevalent and pervasive experienced symptoms even up to three years after diagnosis (O'Gorman et al., 2018).

Therefore, the high occurrence of the above-mentioned problems and their severity highlights the intense demand for psychological interventions intending to diminish the sufferings patients struggle with. To date, many efforts have been made to alleviate the psychological problems of cancer patients among which MBCR has gained remarkable attention in the Oncology sphere. MBCR is a Mindfulness-Based Cancer Recovery (MBCR) that has been successfully applied for the improvement of fatigue (O'Gorman et al., 2018; Carlson et al., 2013; Johns et al., 2015), stress (Zernicke et al., 2016), and sleep disturbances (Garland et al., 2015; Andersen et al., 2013) in cancer patients. Although being effective, we encountered a paucity of research aiming these symptoms in Colorectal and Stomach patients.

Considering the high prevalence of sleep disturbance, stress, and fatigue in these patients along with many other side effects they experience in the course of chemotherapy treatment period and the nature of the MBCR program which is primarily stress-oriented, this study aims to investigate the effectiveness of the MBCR program on stress, sleep disturbances, and fatigue in Colorectal and stomach cancer patients during chemotherapy treatment. This study is the first to assess the effectiveness of the online version of the MBCR program on psychological correlates of patients living with cancer in Iran.

2. MATERIAL AND METHOD

Study design

This is a randomized wait-list controlled trial study design with parallel groups with pre-and post-assessment and two-month follow-up among patients diagnosed with colorectal and stomach cancers.

Procedures

The study duration took place from April 2021 (Recruitment phase) to mid November 2021 (follow-up phase). The sampling was done from "Taleghani" and "Amiralam" Hospitals through convenience sampling in Tehran, Iran. At first, the oncologist encouraged the patients to participate in the study during their chemotherapy period. Patients were then screened for inclusion and

exclusion criteria by a psychiatric interview. Third, the eligible participants received a full explanation of the study nature and randomization process and fillout an informed consent. Fourth, patients were randomly allocated to either the experimental or control group through drawing lots. Fifth, a pre-assessment was run. Sixth, the Experimental group went through 9 weekly sessions of the online MBCR program while the control group received their treatment as usual [TAU]. Both groups were reassessed after the nine-week passing the intervention and two-month follow-up while receiving their normal chemotherapy sessions (Figure 1).

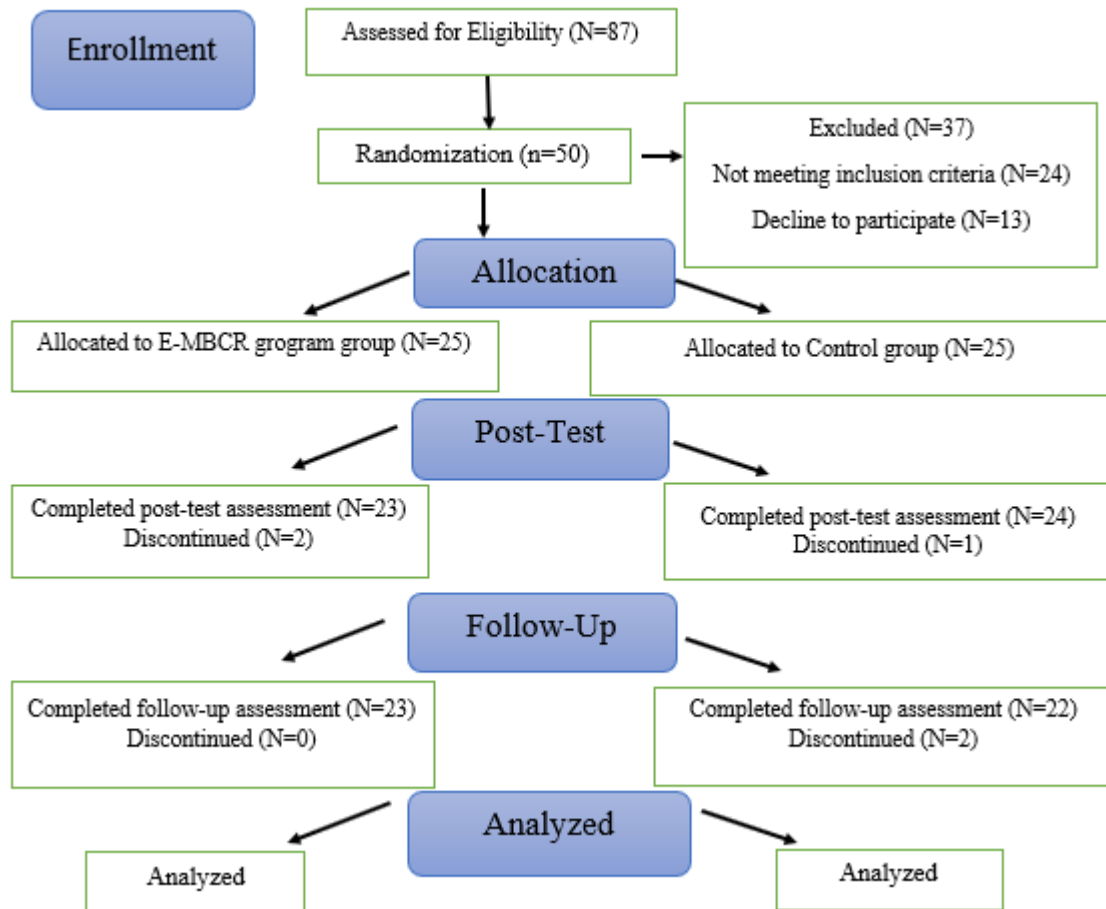


Figure 1 Flow chart of the study procedure

Eligibility

Inclusion criteria are: 1) age range (20 to 65), 2) ability to read and write sufficiently to complete the questionnaires, 3) diagnosis of any Colon or stomach cancer within stage I–III, 4) going under concurrent chemotherapy treatment, 5) access to high-speed Internet, 6) No previous or concurrent participation in a yoga or meditation course, 7) Stating willingness to participate in the intervention and, 8) physical ability do sessions' training.

Exclusion criteria were: 1) concurrent self-reported and psychologists' diagnosis of psychiatric disorder (psychosis, bipolar disorder or substance abuse, suicidal ideation (diagnosis of a depressive, anxiety, or adjustment disorder did not hinder enrollment), 2) use of psychotropic medication, 3) diagnosis of severe medical disease, 4) concurrent psychotherapy treatment, 5) two consecutive absences in treatment, 6) Patients facing death.

Ethical Standards

All patients were informed of the voluntary nature of the study and signed a written informed consent before participation. This study was approved by the Research Ethics Committee of Shahid Beheshti University of Medical Sciences (approval code: IR.SBMU.MSP.REC.1399.542).

Intervention

25 participants (experimental) logged internet for 9 weekly, 90 minutes online MBCR sessions. Because of Covid-induced social distancing and deprivation of many cancer patients of receiving face to face psychological interventions, long-distance, patients' caregivers' preference for stay-at-home practices, and higher convenience; the online MBCR program replaced the face-to-face type. Essential facilities like internet access were provided while MBCR program recordings, manuals, and work books were posted for patients before and during the course. To avoid forgetting sessions, an alert reminder message was sent 2 hours before each session to each participant. The MBCR is a cancer-specific MBSR program, which is modified by Carlson and colleagues, was used in the study (Carlson et al., 2019). Treatment incorporates body awareness, exercises, meditation, gentle yoga, and daily home practices. All sessions consist of three sections: discussion, teaching, and practice. The detail of the MBCR protocol is presented in table 1.

Table 1 MBCR session by session protocol

Week	Content	Techniques learned, exercises and activities
Week 1:	Introduction and familiarizing with orientation	Introduction, explanation of group principles and the concept of mindfulness
Week 2:	Mindfulness	Paying attention to body and breath, starting an exercise named "Beginner's mind"
Week 3:	creating Mindfulness attitudes	Teaching mindfulness frame and awareness of pleasant moments
Week 4:	Mind-body wisdom and healing	"Mind-body" connection. Responding instead of reacting to life events. unpleasant events awareness
Week 5:	The autonomic nervous system balance	Breathing techniques for balancing the nervous system, sleeping techniques.
Week 6:	Mindful coping	How our experience of stress is created through thoughts, beliefs, and personal narratives
Week 7:	Fostering beneficial states of heart and mind	Meditation and imagination and compassionate state for self and other
Week 8:	Awareness expanding and deepening	Beyond the breath: awareness expansion
Week 9:	Moving into the world	reviewing insights obtained and preparing to, integrate practice into day-to-day living

Measurements

Demographic

Patients' demographic characteristics form: The form consists of questions regarding age, sex, marital status, education, and cancer type (table 2).

Stress

The DASS-21: The depression and stress scale is composed of 21-items created by Lovibond & Lovibond (1995). Every 7 questions are allocated to one subscale, all of which range from 0 (*did not apply at all*) to 3 (*applied most of the time*). Participants are asked to rate the level to which they had such experiences (each symptom) during the past week (Lovibond & Lovibond, 1995). In the present study, only 7 questions related to the stress subscale were distributed among participants. Cronbach's alpha 0.70 to 0.95 for the DASS-21S indicates high internal consistency of this scale (Dahm et al., 2013; Henry & Crawford, 2005). In addition, Cronbach's alpha coefficient of 0.80 in cancer patients is a sign of good internal consistency of the scale (Bener et al., 2016). Cronbach's alpha coefficient was .94 and .87 for total score and stress subscale respectively in Iranian population (Asghari et al., 2008).

Fatigue

The European Organization for Research and Treatment of Cancer (EORTC) quality-of-life measure QLQ-C30 is a measure incorporating nine multi-item scales among which three questions are related to fatigue assessing the intensity of symptoms during the past week. Responses are measured on a Likert from 1 to 4 (1 'not at all, 2 'a little', 3 'quite a bit' and 4 'very much'). The scale has been validated and demonstrated acceptable internal consistency $\alpha = 0.54-0.86$ in cancer patients (Aronson et al., 1993). Psychometric properties of the scale have yielded $\alpha = 0.87$ in the Iranian gastric cancer population (Sedighi et al., 2009).

Sleep

The *Insomnia Severity Index* (ISI) is an instrument composed of 7 items that assesses the perceived severity of insomnia over the course of the previous two weeks. The participants were asked to rate the severity sleeping difficulties, maintaining sleep and early morning awakenings, sleep dissatisfaction, level of interference of these sleep difficulties in routine functioning, objective reports of the worsening of sleep problems, and distress-related sleep difficulties. Responses are rated on a Likert scale ranging from 0 to 4 (*not at all to very much*). By summing the seven items, the total score is obtained ranges from 0 to 28 (Morin, 1994). The scale has shown good internal consistency ($\alpha = 0.74$) in the general population (Bastien et al., 2001). The internal consistency was demonstrated by Cronbach's alpha coefficient 90 of ISI in cancer patients (Savard et al., 2005). Research has (2002) reported Cronbach's alpha 0.80 in the Iranian population (Yazdi et al., 2005).

Data analysis

In this study, mixed-model analyses for repeated measures were conducted on the pre-test, post-test, and follow-up outcome sessions.

3. RESULTS

At first, 87 patients were assessed to screen the eligibility criteria among which 37 were excluded and 50 patients were included. 58% of them and 42% of the sample were male and female, respectively. Stomach cancer allocated the highest proportion of the sample. Table 2 depicts the demographic variables of the study.

Table 2 Demographic characteristics of Participants					
Variable		All N (%)	MBCR N (%)	TAU N (%)	P Chisquare
Sex	Male	29 (58%)	13 (52%)	16(64%)	.390
	Female	21(42%)	12(48%)	9 (36%)	
Education	Diploma	20(40%)	10 (25%)	10 (25%)	.502
	Upper diploma	20(40%)	9 (36%)	11(44%)	
	Bachelor	7(14%)	4(16%)	3(12%)	
	Master	2(4%)	2(8%)	----	
	Ph.D.	1(2%)	---	1(4%)	
	Single	2(4%)	1(4%)	1(4%)	
Marital status	Married	35(70%)	19(76%)	16(64%)	.215
	In relation	3(6%)	2(8%)	1(4%)	
	separated	5(10%)	---	5(20%)	
	widowed	5(10%)	3(12%)	2(8%)	
Cancer type	Colon	17(34%)	10(40%)	7(28%)	.648
	Rectum	14(28%)	6(24%)	8(32%)	
	Stomach	19(38%)	9 (36%)	10(40%)	
		Mean (SD)	Mean (SD)	Mean (SD)	t
Age		54.90 (6.64)	53.16 (7.35)	56.64 (5.46)	0.063
MBCR: Mindfulness-Based Cancer Recovery					
Note: (P<0.05)					

Table 2 shows that there are no significant differences between the two groups in sex, education, marital status, and cancer type by *Chi-Square test*. Independent *t*-tests either showed no differences between the two groups in age. There were not any significant differences between these groups in sleep ($t_{(48)} = 1.60$, $p = 0.11$); fatigue ($t_{(48)} = -1.05$, $p = 0.29$), stress ($t_{(48)} = 0.44$, $p = 0.65$) at baseline assessment. Table 3 shows the mean and standard deviations of dependent variables at 3 phases of the study (pre, post, and follow-up). Regarding the statistical significance of the mean scores of ISI, DASS-21S, and QLQ-C30 (fatigue) at different phases, the scores show that our dependent variables changed over time in 3 phases of the study (*i.e.*, pre-test, post-test, and follow-up).

Table 3 Means and Standard Deviations of Variables in Pre-treatment, Post-treatment, and Follow-up Assessments

Variables	Condition	Pre-treatment Mean_(SD)	Post-treatment Mean_(SD)	Follow up Mean_(SD)
ISI	MBCR	16.56 (3.60)	12.82(4.05)	12.60(3.66)
	Control	15.12 (2.65)	14/95(3.14)	14.52(2.96)
DASS-21-STRESS	MBCR	13.32(2.74)	10.30(2.11)	9.34(2.16)
	Control	13(2.32)	12.75(1.72)	13.04(1.73)
QLQ-C30 (FATIGUE)	MBCR	51.11(29.39)	33.34 (20.90)	30.91(15.33)
	Control	59.11(23.94)	70/37(19.01)	74.24(15.48)

MBCR: Mindfulness-Based Cancer Recovery
ISI: Insomnia Severity Index
DASS: Depression Anxiety Stress Scale
QLQ C30: Quality of Life Questionnaire
Note: (P<0.05)

Mixed Analysis of Variance was used to determine the effect of the online version of MBCR. Meeting parametric assumptions was a prerequisite for further analysis. Assumptions of normality were checked using the Kolmogorov-Smirnov test, sphericity was checked using Mauchly's test while equality of variance and covariance were assessed by Leven's test and M-Box test, respectively. If not meeting Mauchly's test, Greenhouse-Geisser correction was used. This study was examined with a 3 (time) \times 2 (group) to assess the main effects of both group and time. P-value < .05 was set in this study (table 4).

Regarding calculated F in between-subject effects, it is evident that total scores of dependent variables are different between the MBCR group and control group. This suggests that the treatment was effective on the scores of the variables. Furthermore, the group * time interaction mean score of ISI, DASS-21 S, and QLQ-c30 (fatigue) in the pre-test, post test, and follow-up assessments were significantly different in MBCR and control groups. This implies that the dependent variables were impacted by both time and group factors.

Table 4 Mixed Analysis (repeated measure of Variance) for ISI, DASS-21, QLQ-C30 (FATIGUE) Scores with Greenhouse- Geisser Correction

Assessments	Statistical Indices		SS	Df	MS	F	P Value	Eta square
ISI	Within group	Time	134.62	1.65	81.37	63.58	0.000	0.59
		Time*group	82.88	1.65	50.10	39.14	0.000	0.47
	Between group	Group	29.68	1	29.68	.89	0.000	0.42
DASS-21 S	Within group	Time	129.05	1.59	80.97	65.20	0.000	0.60
		Time*group	85.14	1.59	53.42	43.01	0.000	0.50
	Between group	Group	137.254	1	137.254	11.74	0.001	0.21

QLQ-C30 (FATIGUE)	Within group	Time	389.77	1.56	248.35	1.58	0.002	0.31
		Time*group	8213.74	1.56	5233.58	33.40	0.000	0.43
	Between group	Group	31137.9 5	1	31137.9 5	28.64	0.000	0.40

MBCR: Mindfulness Based Cancer Recovery

ISI: Insomnia Severity Index

DASS: Depression Anxiety Stress Scale

QLQ: Quality of Life Questionnaire

Note: (P<0.05)

Linear trend analysis of changes in the scores of ISI, QLQ-30 (fatigue), and DASS-21 as in the two groups at three phases of pre-treatment, post-treatment, and twomonthsafter treatment are shown in figure 2-4.

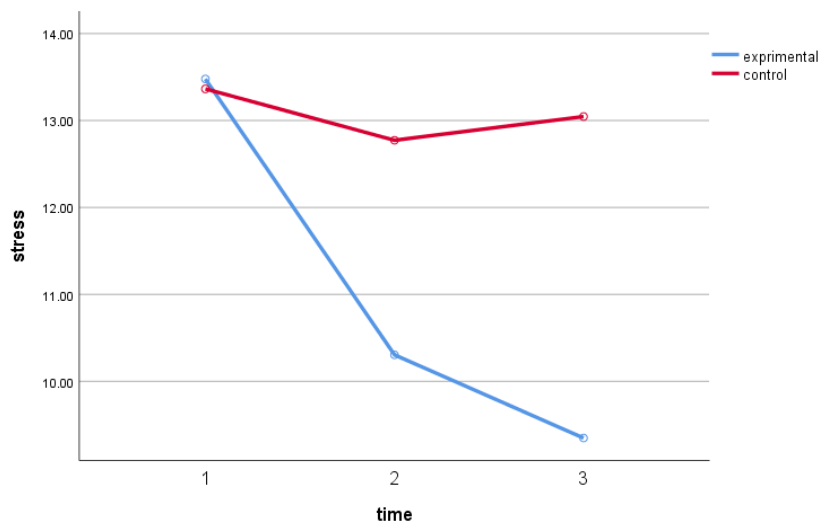


Figure 2 linear trend analyses of the scores of DASS-21S (STRESS) for two groups in pretest, post-test, and follow-up

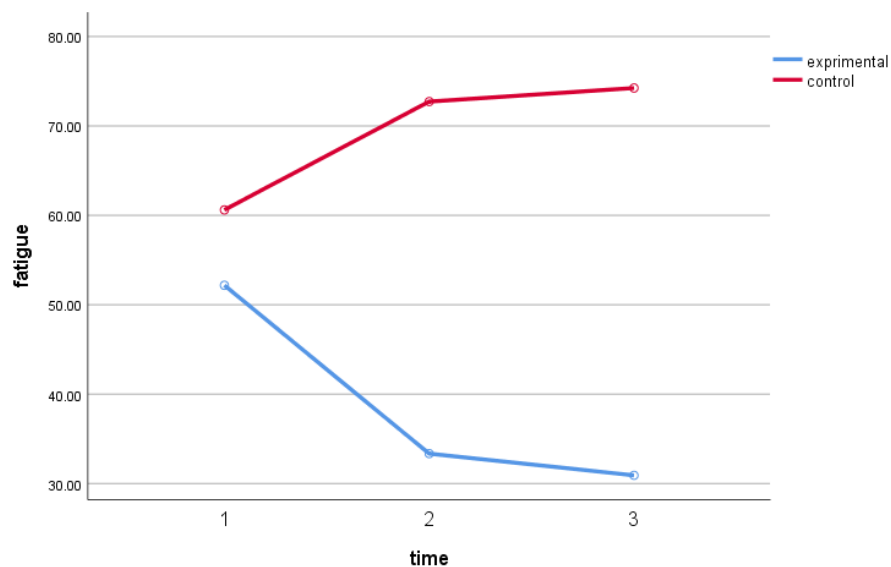


Figure 3 linear trend analyses of the scores of QLQ-C30 subscale (Fatigue) for two groups in pretest, post-test, and follow-up

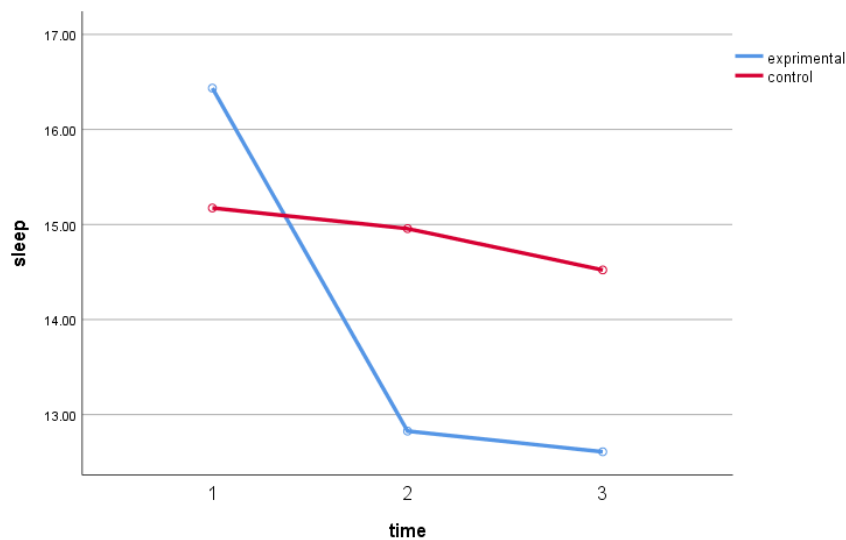


Figure 4 linear trend analyses of the scores of ISI (SLEEP) for two groups in pretest, post-test, and follow-up

Finally, the post-hoc Bonferroni test was run for the sake of pairwise comparison and it showed that there was a significant difference between the scores of the pre-test with post-test and follow-up in the experimental group in a way that the scores are significantly in a declining trend. The difference between posttest and follow-up was not significant for Fatigue and sleep problems implying the pervasiveness of the treatment (table 5). Surprisingly, this declining trend continues significantly from post-test to follow-up in stress scale.

Table 5 Pairwise Comparison

Assessment		Mean difference	S.E	Sig
ISI	Pretest-posttest	3.61	0.24	0.000
	Pretest-follow up	3.82	0.29	0.000
	Posttest-follow up	0.21	0.18	0.78
DASS-21 S	Pretest-posttest	3.17	0.25	0.000
	Pretest-follow up	4.13	0.32	0.000
	Posttest-follow up	.95	0.21	0.001
QLQ-c30(FATIGUE)	Pretest-posttest	18.83	3.15	0.000
	Pretest-follow up	21.26	4.01	0.000
	Posttest-follow up	2.43	2.08	0.77

MBCR: Mindfulness-Based Cancer Recovery
ISI: Insomnia Severity Index
DASS: Depression Anxiety Stress Scale
QLQ: Quality of Life Questionnaire
Note: (P<0.05)

4. DISCUSSION

Our purpose in the present study was to investigate the effectiveness of an online version of a mindfulness-based cancer recovery program (E-MBCR) on the psychological problems of colorectal and stomach cancer patients. Overall, the results indicate that the E-MBCR can reduce the study variables' severity and this is in line with multiple studies showing the beneficial effects of MBCR on psychological correlates of cancer patients (Zernicke et al., 2013; Blaes et al., 2016). Consistent with our hypothesis, a trend of improved cancer-related stress was detected based on the patients' DASS-21 stress response profile in the MBCR group, both in post-test and follow-up. This is in line with the results of Zernick and colleagues (2014) who showed significant improvements in stress symptoms of cancer patients following E-MBCR ($d = 0.49$, $p = .021$).

In our study, the decreasing trend of stress reduction continued even in follow-up compared to post-test. It is hypothesized that after mindfulness meditation, awareness of internal experiences is created. The non-evaluative manner patients are encouraged to include in their emotions, cognitions, and behaviors throughout the program will undoubtedly shape a space to adopt alternative ways to respond to negative emotional states (Shapiro et al., 2006). These results are in line with previous research indicating that participation in mindfulness-based interventions is correlated with improved psychological outcomes in cancer populations (Bränström et al., 2010; Garland et al., 2013; Dobkin & Zhao, 2011). The non-judgmental component of mindfulness offers a lifestyle that allows patients to accept uncertainty and learn to embrace the inherent inability of human kind to control or change the disease progression course (Carlson, 2016) and engage with less rumination and worry (Kabat-Zinn, 2003). Thus, mitigation of stress happens through self-regulation (Tang et al., 2015). Moreover, it has been reported that a balance of sympathetic and parasympathetic responses is created after mindfulness learning which prompts body relaxation (Baer, 2003). These are in accordance with studies showing MBSR programs suggesting improved stress and anxiety in cancer patients (Cramer et al., 2012; Piet et al., 2012; Zainal et al., 2013).

Our data also showed that the sleep disturbance scores went on declining trends both in post-test and follow-up assessments compared to pre-test in the experimental group. This is consistent with the findings of Garland (2015), who demonstrated improved sleep problematic beliefs in cancer patients after MBCR (Garland et al., 2015). In a similar vein, John et al., (2015) reported improvements in objective sleep parameters (e.g., fewer waking bouts and more sleep times) in 78% of the mindfulness group cancer patients (Johns et al., 2015). Retainment of sleep improvements in the follow-up phase also goes in line with the study by Bachanova who reported improvements in sleep after MBCR during a couple of months (Blaes et al., 2016). First, the program itself encompassed techniques focusing on sleep difficulties. Second, the beneficial effect of MBCR on sleep disturbance may be due to the augmented responsiveness to bodily cues like sleepiness and even separation of routine tensions and stresses which inhibits restful sleep. Another explanation is that the non-judging manner aspect of mindfulness may improve sleep quality by tapping stress states and buffering everyday tensions, hence leading to better sleep.

Furthermore, our data showed that total scores of CRF decreased after E-MBCR intervention both at the post-intervention and follow-up phase. This is consistent with the studies reporting the influential effects of a mindfulness-based intervention on fatigue in cancer patients (Thornton et al., 2014). Johns and colleagues (2015) also showed the effects of mindfulness on cancer-related fatigue in a 7-week MBSR program compared to those in a wait-list control group. The sleep-focusing exercises and yoga component of MBCR may have reduced fatigue. Another explanation is that fatigue may be improved through the channel of improved insomnia, as better sleep quality results in more freshness as previous research has repeatedly noticed the relation between fatigue and insomnia (Roscoe et al., 2007). In general, it appears that E-MBCR represents a treatment option for cancer patients with stress, fatigue, and sleep problems.

The results of the present study should be noticed within some limitations. First, though the reassurance was given by the researcher regarding the confidentiality of the responses, collected data may be distorted by desirability bias as the assessments were self-report ones. Second, due to the time limitations, researchers had to suffice on two months follow-up. More research in this area is needed addressing the longitudinal pervasiveness of improvements beyond two months. Third, the study was conducted in an individual therapist-patient format. In future studies, it would be intriguing to explore the effectiveness of group format therapy. Fourth, including other cancer types in future research designs could be a future research opportunity.

5. CONCLUSION

In conclusion, data showed that the online MBCR program could duly be beneficial in reducing the psychological problems of cancer patients. This means that even treatment directions need to update to new technology world, even though the limitations. Regarding the novelty of the research, especially in Iran, the need for more prospective research exploring the online version of the program is sensed.

Authors' contribution

Conceptualization: Ahmad, Yousefi; Methodology and Formal analysis: Ahmad, Yousefi, Mohsen Saberi; Investigation, Resources: Ahmad, Yousefi, Maryam Aslezaker; Data collection: Behzad Asanjarani, Mojtaba Ghadiany; Writing and original draft preparation: Ahmad Yousefi; review and editing: Mahdi Jafari; Supervision: Maryam Aslezaker; Project administration: Abbas Masjedi Arani. All authors have read and agreed to the published version of the manuscript.

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Conflict of interests

The authors declare that there are no conflicts of interests.

Data and materials availability

All data associated with this study are present in the paper.

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